

REMARKS

Claims 199, 201-202, 206-213, and 225-287 are pending in the application. Claims 199, 201-202, and 206-213 have been amended. Claims 1-198, 200, 203-205, and 214-224 have been canceled without prejudice. New claims 225-287 have been added. The right to prosecute the subject matter of any canceled claim in one or more continuation, continuation-in-part or divisional applications is hereby reserved. No new matter has been added.

Support for the amended and new claims can be found in the table below.

Amended or New Claim	Support
199	Page 1, line 18; Page 6, lines 12-13 and lines 17-19; Page 7, lines 4-9; Page 17, lines 13-17 and lines 30-31; Page 18, line 5 and lines 14-15
201	Page 6, line 19; Page 23, lines 23-25
202	Page 23, lines 25
206	Page 18, line 13 to Page 19, line 8
207	Page 18, lines 13-32; Page 19, lines 18-20
208	Page 21, line 30
209	Page 22, lines 4-5
210	Page 12, line 17; Page 22, lines 8-9
211	Page 12, lines 17-18; Page 22, lines 8-11
212	Page 12, line 4; Page 22, line 32
213	Page 51, line 6
225	Page 1, line 18; Page 6, lines 12-13 and lines 17-19; Page 7, lines 4-9; Page 17, lines 12-14; Page 70, lines 23-4
226	Page 37, line 11
227	Page 18, line 24
228	Page 18, lines 24-25

229	Page 19, line 20
230	Page 19, line 20
231	Page 18, line 28-29
232	Page 11, line 22
233	Page 11, line 11; Page 65, line 19
234	Page 65, line 24
235	Page 11, line 31; Page 12, line 4; Page 21, line 30; Page 22, line 8; page 66, line 29
236	Page 12, line 26; Page 21, line 31
237	Page 11, line 22
238	Page 11, line 11; Page 65, line 19
239	Page 65, line 24
240	Page 11, line 31; Page 12, line 4; Page 21, line 30; Page 22, line 8; page 66, line 29
241	Page 12, line 26; Page 21, line 31
242	Page 1, line 18; Page 6, lines 12-13 and lines 17-19; Page 7, lines 4-9; Page 17, lines 12-14; Page 18, line 5; Page 30, line 10; Page 70, lines 23-4
243	Page 23, lines 23-25
244	Page 23, lines 25
245	Page 21, line 30
246	Page 22, lines 4-5
247	Page 12, line 17; Page 22, lines 8-9
248	Page 12, lines 17-18; Page 22, lines 8-11
249	Page 12, line 4; Page 22, line 32
250	Page 51, line 6
251	Page 37, line 11
252	Page 11, line 22

253	Page 11, line 31; Page 12, line 4; Page 21, line 30; Page 22, line 8; page 66, line 29
254	Page 12, line 26; Page 21, line 31
255	Page 11, line 11; Page 65, line 19
256	Page 65, line 24
257	Page 1, line 18; Page 6, lines 12-13 and lines 17-19; Page 7, lines 4-9; Page 17, lines 12-14; Page 18, line 5; Page 30, line 10; Page 70, lines 23-4
258	Page 11, line 22
259	Page 11, line 11; Page 65, line 19
260	Page 65, line 24
261	Page 11, line 31; Page 12, line 4; Page 21, line 30; Page 22, line 8; page 66, line 29
262	Page 12, line 26; Page 21, line 31
263	Page 18, line 13 to Page 19, line 8; Page 19, line 20
264	Page 18, lines 13-32; Page 19, lines 18-20
265	Page 18, line 24
266	Page 18, lines 24-25
267	Page 19, line 20
268	Page 19, line 20
269	Page 18, line 28-29
270	Page 37, line 11
271	Page 6, line 19; Page 23, lines 23-25
272	Page 23, lines 25
273	Page 21, line 30
274	Page 22, lines 4-5
275	Page 12, line 17; Page 22, lines 8-9

276	Page 12, lines 17-18; Page 22, lines 8-11
277	Page 12, line 4; Page 22, line 32
278	Page 51, line 6
279	Page 37, line 11
280	Page 6, line 19; Page 23, lines 23-25
281	Page 23, lines 25
282	Page 21, line 30
283	Page 22, lines 4-5
284	Page 12, line 17; Page 22, lines 8-9
285	Page 12, lines 17-18; Page 22, lines 8-11
286	Page 12, line 4; Page 22, line 32
287	Page 51, line 6

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 199-224 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Claim 199 has been amended to delete the language “wherein the substrate and the at least one third substance do not have opposite charges.” Furthermore, claims 200, 203-205, and 214-224 have been canceled without prejudice, rendering the rejection of these claims under 35 U.S.C. § 112, first paragraph, moot.

Likewise, new claims 225-287 do not recite the language “wherein the substrate and the at least one third substance do not have opposite charges.”

In view of the amendment to claim 199 and the cancellation of claims 200, 203-205, and 214-224, it is believed that the presently pending claims meet the requirements of 35 U.S.C. § 112, first paragraph. Consequently, it is believed that the rejection of claims 199-224 under 35 U.S.C. § 112, first paragraph, has been overcome and should be withdrawn.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 199-224 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

Claim 199 has been amended to delete the language “wherein the second component is more soluble than the first substance in the liquid medium.” Furthermore, claims 200, 203-205, and 214-224 have been canceled without prejudice, rendering the rejection of these claims moot.

Likewise, new claims 225-287 do not recite the language “wherein the second component is more soluble than the first substance in the liquid medium.”

In view of the present amendment to claim 199 and the cancellation without prejudice of claims 200, 203-205 and 214-224, it is believed that the presently pending claims meet the requirements of 35 U.S.C. §112, second paragraph. It is believed, therefore, that the rejection under 35 U.S.C. § 112, second paragraph, has been overcome and should be withdrawn.

Rejection Under 35 U.S.C. §102(b)

Claims 199-208 and 213-220 have been rejected under 35 U.S.C. § 102(b), as being allegedly anticipated by U.S. Patent No. 4,731,210 to Weder *et al.* (“Weder”).

Claim 199 has been amended to recite that a macromolecule is bound to the surface of the vesicle, and that the nonionic detergent destabilizes the vesicle. Nowhere does Weder teach that a macromolecule is bound to the surface of a vesicle, or that a nonionic detergent destabilizes the vesicle. In stark contrast, Weder teaches that the pharmaceutical substance is *incorporated or absorbed into* a liposome (the INCORPORATION RATE column in the TABLE at col. 11 and 12, col. 14, lines 12-13, and claim 4, lines 5-7), and that the “solubilizing agents” are *removed or inactivated* (Abstract, lines 9-10; col. 5, lines 14 and 66-67; col. 6, lines 59-60; col. 8, line 14). As claims 201-202 and 206-213 depend from claim 199, amended as above, Weder does not anticipate these claims, as well.

Furthermore, claims 200, 203-205, and 214-224 have been canceled without prejudice, rendering the rejection of these claims moot.

New claims 225-287 also recite that a macromolecule is bound to the surface of the vesicle. New claims 225-241 and 263-278 recite that the nonionic detergent destabilizes the vesicle. New claims 242-262 and 279-287 recite that sodium cholate destabilizes the vesicle. As such, Weder does not anticipate the new claims as well.

In view of the above, it is believed that the rejection of the claims under 35 U.S.C. § 102(b) as being anticipated by Weder has been overcome and should be withdrawn.

Rejection Under 35 U.S.C. §103(a)

Claims 199-224 have been rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Weder alone or in combination with WO 92/03122 to Cevc (“Cevc”).

Weder does not alone or in combination with Cevc render the present claims obvious. As stated above, claim 199 has been amended to recite that a macromolecule is bound to the surface of the vesicle, and that the nonionic detergent destabilizes the vesicle. Weder is limited to a pharmaceutical substance that is incorporated or absorbed into a liposome, and is further limited to where the “solubilizing agents” are removed or inactivated. Nowhere does Weder teach or suggest that a macromolecule is bound to the surface of a vesicle, or that a nonionic detergent

destabilizes the vesicle. Cevc does not cure the deficiency of Weder because, like Weder, Cevc also does not teach or suggest that a macromolecule is bound to the surface of a vesicle.

Furthermore, claims 200, 203-205, and 214-224 have been canceled without prejudice, rendering the rejection of these claims moot.

For the reasons discussed above, it is believed Weder also does not render new claims 225-287 obvious.

Accordingly, in light of the present amendments and cancellations without prejudice, it is believed that the rejection of the claims as being unpatentable under 35 U.S.C. § 103(a) over Weder either alone or in combination with Cevc has been overcome and should be withdrawn.

Provisional Obviousness-Type Double Patenting Rejections

Claims 199-224 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 31, 38 and 70-76 of copending application no. 09/621,574 and over claims 1-66, 80-81 and 88-100 of copending application no. 10/357,618.

The provisional obviousness-type double-patenting rejections are hereby acknowledged. It is respectfully requested that the provisional rejections be addressed upon the Examiner's indication that the present claims are otherwise allowable.

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Conclusion

It is respectfully requested that the Examiner enter the present amendment in light of the foregoing remarks and it is believed that all the claims are in condition for allowance. If the Examiner believes that a telephone interview would help expedite the successful prosecution of the claims, the undersigned attorney would be grateful for the opportunity to discuss any outstanding issues.

Please charge any payments due to Wilmer Cutler Pickering Hale and Dorr LLP Deposit Account No. 08-0219.

Respectfully submitted,
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